

PART 226—CURRENT GOOD MANUFACTURING PRACTICE FOR TYPE A MEDICATED ARTICLES

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SOURCE: 40 FR 14031, Mar. 27, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 226.1 Current good manufacturing practice.

(a) The criteria in §§ 226.10 through 226.115, inclusive, shall apply in determining whether the methods used in, or the facilities and controls used for the manufacture, processing, packing, or holding of a Type A medicated article(s) conform to or are operated or administered in conformity with current good manufacturing practice to assure that a Type A medicated article(s) meets the requirements of the act as to safety, and has the identity and strength, and meets the quality and purity characteristics which it purports or is represented to possess, as required by section 501(a)(2)(B) of the act. The regulations in this part 226 permit the use of precision, automatic, mechanical, or electronic equipment in the production of a Type A medicated article(s) when adequate inspection and checking procedures or other qual-

ity control procedures are used to assure proper performance.

(b) In addition to maintaining records and reports required in this part, Type A medicated articles requiring approved NADAs are subject to the requirements of § 514.80 of this chapter. Similarly, Type A medicated articles listed in the index are subject to the requirements of § 516.165 of this chapter.

[40 FR 14031, Mar. 27, 1975, as amended at 68 FR 15364, Mar. 31, 2003; 72 FR 69120, Dec. 6, 2007]

§ 226.10 Personnel.

The key personnel and any consultants involved in the manufacture and control of the Type A medicated article(s) shall have a background of appropriate education or appropriate experience or combination thereof for assuming responsibility to assure that the Type A medicated article(s) has the proper labeling and the safety, identity, strength, quality, and purity that it purports to possess.

Subpart B—Construction and Maintenance of Facilities and Equipment

§ 226.20 Buildings.

Buildings in which Type A medicated article(s) are manufactured, processed, packaged, labeled, or held shall be maintained in a clear and orderly manner and shall be of suitable size, construction and location in relation to surroundings to facilitate maintenance and operation for their intended purpose. The building shall:

(a) Provide adequate space for the orderly placement of equipment and materials used in any of the following operations for which they are employed to minimize risk of mixups between different Type A medicated article(s), their components, packaging, or labeling:

(1) The receipt, sampling, control, and storage of components.

(2) Manufacturing and processing operations performed on the Type A medicated article(s).

(3) Packaging and labeling operations.